REMARKS

Claims 1-6, 11, 17, 32-37 and 42-56[1] are pending. Claims 5, 13-15, 32-37 and 42-56 have been withdrawn and Claims 1-4, 6, 11, 12, 16 and 17 have been examined. By way of this amendment claims 2- 4 have been cancelled. Claim 1 has been amended so as to limit element (a) to gabapentin. Claim 57 has been added which further limits element (b) to dextromethorphan. Support for this amendment can be found throughout the specification and the claims as originally filed. No new matter has been added.

In the Office Action, claim 4 has been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. As sated above claim 4 has been cancelled and therefore the rejection is now moot.

In the Office Action, claims 1-4, 6, 11, 12, 16 and 17 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,767,130 to Olney et al. (herein with referred to as "Olney") in view of U. S. Patent No. 6,284,794 to Olesen et al. (herein with referred to as "Olesen"). The Applicants respectfully traverse the rejection.

In making the rejection, the Examiner stated Olney teaches that "compounds with (sic) act as GABA agonists provide protection against NMDA antagonist neurotoxicity (col. 9, lines 5-55)." (See Office Action top of page 5). However, a review of this section indicates that the paraphrasing used by the Examiner does not accurately describe what this section teaches. Instead, this section merely states that "

> "it has been postulated ... that the efficacy of certain barbiturates in preventing the neurotoxic actions of NMDA antagonists stems from their

[1] In the Office Action the Examiner incorrectly stated that there were only 55 claims, however, a preliminary amendment filed on July 16, 2004 had 56 claims. Since claim 56 is directed to a method the Applicants have listed the claim as withdrawn.

> ability to act as direct GABA agonists that can activate GABA type A ($GABA_A$) receptors even in the absence of GABA." (See Olney col. 9 lns 24-30).

Further down column 9 cited by the Examiner it discusses diazepam as another possible "safener agent". It is stated that the

> "observations that diazepam . . . does not, like barbituantes, act as a direct GABA agonist even in the absence of GABA, rather the action of diazepam is dependent upon GABA being present and is limited to potentiating the action of GABA. ""(See Olney col. 9 lns 40-47).

Even further down column 9 to column top of column 10 in Olney there are listed totally different classes of compounds that can be used as "safener agents."

Thus, the fact that there are many different types of broad classes of safener agents discussed in Olney, and that each class of safener agents discussed can have many different compounds that fall within, provides an enormous number of compounds left to one skilled in the art to choose from should one want to use a safener agent in a composition. Not to mention the fact that GABA analogs are only discussed in combination with reference to certain types of barbiturates and in this discussion it is stated that it is only a "postulated theory" that the efficacy of certain barbiturates in preventing the neurotoxic actions of NMDA antagonists stems from their ability to act as direct GABA agonists that can activate GABA type A ($GABA_A$) receptors even in the absence of GABA.

Thus one reading this section would merely gather that there are many different types of "Safener Agents for Preventing Adverse Side Effects of NMDA Antagonist Drugs" and would not be directed to GABA analogs, let alone gabapentin in particular.

Moreover, since this column also discusses that diazepam as a possible safener agent and states that it does not "act as a direct GABA agonist" one skilled in the art would not in fact not be led to GABA agonists at all but would instead be exposed to broad classes of "safener agents" each of which contain many different compounds.

This is confirmed even further by the fact that Examiner has acknowledged that Olney does not list gabapentin as a GABA analog but instead relied on Olsen to correct this factual defect. A review of Olsen indicates that many GABA agonists, GABA uptake inhibitors, GABA transaminase inhibitors, as well as many other types of inhibitors and analogs that can be used as safener agents that treat tension-type headaches with inhibitors of "Nitric Oxide and Nitric Oxide Synthase." Gabapentin is but one of many, many different compounds listed in this 96-column patent. Thus one would not be led to gabapentin at all, to the exclusion of the many different safener agents discussed in Olney and Olesen.

It is fundamental that it is impermissible within the framework of §103 to *pick and choose from any one reference only so much of it as will support a given position*, to the exclusion of other parts necessary to achieve full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 147 USPO 391,393 (CCPA 1965). In addition, as is fundamental, "[a] prior art reference must be considered in its entirety, *i.e.*, as a whole, *including portions that would lead away from the claimed invention.*" (Underline original, bold emphasis added). *See* MPEP § 2141.02 at 2100-95. A primary reference, such as Olney, that when read in its entirety actually "teaches away" from the claimed invention by the

mere fact that many other safener agents are provided, ***is*** sufficient to show that one would ***not*** have combined the references. *See* MPEP § 2145 at 2100-123 ("It is improper to combine references where the references teach away from their combination."). Here, as stated above, Olney as well as Olsen explicitly teaches many, many, safener agents that can be used, and does not explicitly state that gabapentin in particular be used with a nontoxic antagonist for the NMDA receptor. And that is what one of ordinary skill in the art would have taken away from Olney and Olsen. And that, is not suggestive of what is claimed.

Finally, it is clear from the Examiner's limited reading and choosing only the compounds from the prior art that support the Examiner's position without any clear suggestion or motivation to do so that the Examiner has used impermissible hindsight reconstruction in order to arrive at the claims. A practice that has long been seen as being rejected by the Patent Office and the Courts.

Accordingly, it is respectfully submitted that the Examiner has not meet his burden of establishing a *prima facie* case of the cited art and for this reason alone the Appellants respectfully request that the rejection of claims 1, 6, 11, 12, 16 and 17 under 35 U.S.C. §103(a) over Olney in view Olesen be reconsidered and withdrawn.

As for new claim 57, which further limits the at least one nontoxic antagonist for the NMDA receptor to dextromethorphan, the arguments discussed above for using gabapentin as the GABA analog are also true for choosing dextromethorphan as the nontoxic antagonist for the NMDA receptor. Many, Many different nontoxic antagonists for the NMDA receptor are listed in Olney and Olsen and dextromethorphan is not singled out as being preferred so that one skilled in the art

would be led to dextromethorphan as the nontoxic antagonist for the NMDA receptor. Thus, choosing dextromethorphan as the nontoxic antagonist for the NMDA receptor is again *picking and choosing from any one reference only so much of it as will support a given position*, which, as stated above, is impermissible within the framework of §103.

Moreover, it is apparent that, based on the rejection, the references of the rejection in total and the Examiner's reasoning, that the rejection was based on hindsight recreation of the claims using the teachings of the present application as a blue print of the composition. *In re Wesslau*, 147 USPQ 391,393 (CCPA 1965); *see In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988); *see In re Gorman*, 933 F.2d 982, 18 U.S.P.Q. 2d 1885 (Fed. Cir. 1991) ("It is impermissible ... simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps."). *See also, Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

As stated in *In re Fritch*,

> It is impermissible to use the claimed invention as an instruction manual or template to piece together the teachings of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. In re Fritch, 23 U.S.P.Q. 1781, 1783, 1784 (Fed. Cir. 1992).

Indeed, the Federal Circuit has repeatedly cautioned against using hindsight by using the Applicants' disclosure as a blueprint to reconstruct the claimed subject

matter out of isolated teachings from the prior art. See also Grain Processing Corp. V. American Maize-Products Co., 840 F.2d 902, 5 U.S.P.Q. 2d 1788 (Fed. Cir. 1988).

Since as discussed above, Olney/Olesen does not teach or specifically suggest the combination of gabapentin as a GABA analog with dextromethorphan, it is clear that the Examiner has used hindsight to pick and choose among the isolated disclosures of the prior art to deprecate the present claims. For these reasons it is respectfully asserted that new claim 57 is also patentable over the cited references.

Finally, it is noted that the requirement for the Examiner to provide some sort of teaching, suggestion, incentive or inference in the applied prior art in order to maintain a *prima facie* case of obviousness has been once again confirmed in the recent *Supreme Court case KSR Int'l.Co., V. Teleflex, Inc.* As stated by the USPTO, in interpreting this decision, "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." *(See Official Memorandum issued by Deputy Commissioner for Patent Operations dated May 3, 2007).*

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims , 6, 11, 12, 16 and 17 presently pending in the application and claim 57 as added. Are in condition for allowance.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Respectfully submitted,

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